PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Michael Stephen Austin	Examiner: Reimers, Annette R.
Application No.: 09/556,671	Group Art Unit: 3733
Filed: April 24, 2000	Docket: 792-21 RCE2
For: ANATOMICALLY CORRECT ENDOLUMINAL PROSTHESES	Dated: January 15, 2009

Confirmation No.: 7622

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Dated: January 15, 2009

Signature: Barbara Thomas/

RESPONSE TO THE NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Sir:

The Appellant has received a Notification of a Non-Compliant Appeal Brief, dated December 22, 2008, a reply to which is due January 22, 2009. The Notification alleged that the appeal brief did not refer to the drawings for the elements in the Section V or the Summary of Claimed Subject Matter of the claimed subject matter. This Response correctly refers to the appropriate figures and element numbers in the Section V or the Summary of Claimed Subject Matter. As the Notification failed to state that it only requires submission of the corrected section, the entire Appeal Brief is included hereinafter.

This Response is being timely filed on or before January 22, 2009.

I. Real Party In Interest

The real party in interest is Scimed Life Systems, Inc., the assignee of the entire right, title and interest in and to Application No. 09/556,671.

II. Related Appeals and Interferences

No related appeals or interferences are known to the Appellant or the Appellant's legal representative which will directly affect or be directly affected by or have bearing on the Board's decision in this appeal.

III. Status of Claims

Claims 1-9, 11-15, 17-24, 27-31, 33-37 and 42-45 are presently pending in the application and stand as being finally rejected. These claims are being appealed.

IV. Status of Amendments

In response to the final rejection mailed February 26, 2007, a Notice of Appeal was filed on May 29, 2007 without further amendments. In addition, no further amendments have been presented after the filing of this appeal.

V. Summary of Claimed Subject Matter

The present invention is directed to an anatomically curved endoluminal prosthesis. When a straight stent is deployed into a curved bodily lumen, the patient's anatomy is induced to conform to the shape of the deployed stent. (Specification, page 2, lines 3-4). This may

result in undesirable localized stresses, thrombosis or emboli formation and other complications. (Specification, page 2, paragraphs beginning with "The influence of a..." and "In addition to the influence..."). With the use of the anatomically curved endoluminal prosthesis of the present invention, the deployed stent conforms to the patient's anatomy without detrimental effects caused by imposing an unnatural shape on the patient's anatomy. (Specification, page 2, lines 4-5; page 3, paragraph beginning with "As exemplified above...").

Independent claim 1 is directed to an endoluminal prosthesis. (Specification, page 4, first full paragraph beginning with "It is a further object...", lines 1-2). The endoluminal prosthesis **{1, Fig. 1A & 5}** comprises a proximal end, a distal end and a hollow tubular body comprising a stent scaffold having V-shaped or quadrilateral-shaped cells. (Specification, page 21, paragraph beginning with "Once the wire...", lines 4-10; Figs. 1A and 2). The stent scaffold consists essentially of helically wound undulating wires **{5, Figs. 2 & 21}** having alternating peaks **{3, Fig. 2}** and valleys **{4, Fig. 2}** to define turns thereat. (Specification, page 8, paragraph beginning with "Fig. 1 shows...", lines 4-5; page 9 lines 4-5 of the paragraph bridging pages 8 and 9). The hollow tubular body comprises at least one segment of curvature **{23, Fig. 5}**. (Specification, page 11, paragraph beginning with "The stent 1...", lines 1-2). The segment of curvature **{23, Fig. 5}** comprises an inside of the curvature and an outside of the curvature. The wires **{5, Figs. 2 & 21}** and their turns **{3,4, Figs. 2 & 21}** are distributed substantially equally and uniformly displaced along the length of the prosthesis **{1, Fig. 1A & 5}**, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature **{23, Fig. 5}**, to provide a constant pitch of the wires **{5, Figs. 2 & 21}** therealong. (Specification, page 20, first fill paragraph, lines 1-11; page 20, last paragraph, line 6, to page 21, line 4).

Independent claim 23 is directed to an endoluminal prosthesis. (Specification, page 4, first full paragraph beginning with "It is a further object...", lines 1-2). The endoluminal prosthesis **{1, Fig. 1A & 5}** comprises a proximal end, a distal end and a hollow tubular body

comprising a stent scaffold having V-shaped or quadrilateral-shaped cells consisting essentially of helically wound undulating wires **{5, Figs. 2 & 21}** having alternating peaks **{3, Fig. 2}** and valleys **{4, Fig. 2}** to define turns thereat. (Specification, page 21, paragraph beginning with "Once the wire...", lines 4-10; Figs. 1A and 2; page 8, paragraph beginning with "Fig. 1 shows...", lines 4-5; page 9 lines 4-5 of the paragraph bridging pages 8 and 9). The hollow tubular body comprises at least one segment of curvature **{23, Fig. 5}**. (Specification, page 11, paragraph beginning with "The stent 1...", lines 1-2). The segment of curvature **{23, Fig. 5}** comprising an inside of the curvature and an outside of the curvature. The wires **{5, Figs. 2 & 21}** and their turns **{3,4, Figs. 2 & 21}** are distributed substantially equally and uniformly displaced along the length of the prosthesis **{1, Fig. 1A & 5}**, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature **{23, Fig. 5}**. (Specification, page 20, first fill paragraph, lines 1-11; page 20, last paragraph, line 6, to page 21, line 4). The wires **{5, Figs. 2 & 22}** have an increased pitch **{166, Fig. 22}** at the outside segment and have a reduced pitch **{164, Fig. 22}** at the inside segment when disposed on a straight mandrel **{162, Fig. 22}**. (*Id.*) The resulting hollow tubular body is geometrically shaped and sized to approximate an anatomical shape.

As set forth in dependent claims 11 and 27, the wires **{5, Figs. 2 & 21}** of prosthesis of the present invention may comprise a shape memory alloy. (Specification, page 5, paragraph beginning with "In a preferred embodiment...", line 6).

As set forth in dependent claims 12 and 28, the wires **{5, Figs. 2 & 21}** of prosthesis of the present invention may comprise a super elastic alloy. (Specification, page 5, paragraph beginning with "In a preferred embodiment...", line 6).

As set forth in dependent claims 14 and 30, the wires **{5, Figs. 2 & 21}** of prosthesis of the present invention may include nitinol wires. (Specification, page 9, line 6-7).

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:

I. Whether claims 1-9, 13, 15, 17-24, 27, 29, 31, 33-37 and 42-45 are unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 5,122,154 to Rhodes?

II. Whether claims 12, 14, 28 and 30 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,122,154 to Rhodes in view of U.S. Patent No. 4,994,071 to MacGregor?

III. Whether claims 11 and 27 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,122,154 to Rhodes in view of U.S. Patent No. 4,553,545 to Maass et al.?

VII. Argument

I. Rejection under 35 U.S.C. §102(b) over U.S. Patent No. 5,122,154 to Rhodes

Claims 1-9, 13, 15, 17-22 and 44-45

U.S. Patent No. 5,122,154 to Rhodes (hereinafter "Rhodes") describes an intraluminal graft having a plurality of stents. The stents do not include undulating wires, but rather are pivotally connected straight stent struts. Rhodes describes it stents, as follows:

> **[E]ach stent member 30 basically comprises a plurality of interconnected links or struts 32. Each of the links is an elongated rigid member formed of stainless steel or some other suitable biocompatible material, e.g., tantalum, plastic. Each link has a pair of ends 32A and 32B and is joined to an associated link via a pivotable joint 34. Each joint 34 is made up of one end 32A of one link and the other end 32B of the immediately adjacent link. The link ends 32A and 32B are connected by any suitable means, e.g., a deformable member, a pin, etc., to enable the links to pivot outward with respect to each other so that the angle therebetween increases, yet which precludes the links from pivoting backward toward each other. When so**

arranged the links form a zig-zag pattern. (Rhodes, column 6, lines 32-46) (emphasis added)

Such description is consistent with the detailed stent drawings of Rhodes, i.e. Figures 8 and 9, which are reproduced below for convenience of the Board.

FIG.8

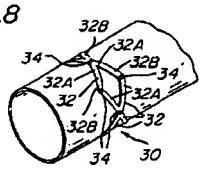
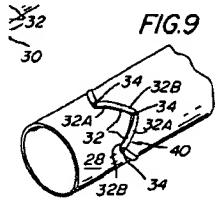


FIG.9



The straight elongate strut members of Rhodes do not read on the stents of the invention as set forth in the independent claims because the straight and elongated strut members of Rhodes are not helically wound undulating wires. Even though the straight struts of Rhodes are described as being pivotally connected, such connections do not make those straight struts as being helical[1] struts or wound[2] struts because the straight, short struts are merely diagonally disposed over a minor portion wall. Further, none of the straight wire segments themselves of Rhodes have alternating peaks and valleys as the wires are described as being straight segments.

Thus, Rhodes fails to disclose, *inter alia*, a stent scaffold consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat, as set forth in independent claim 1.

Assuming *arguendo* that one could somehow read the strut members of Rhodes to be undulating wires, Rhodes still fails to disclose each and every limitation as set forth in

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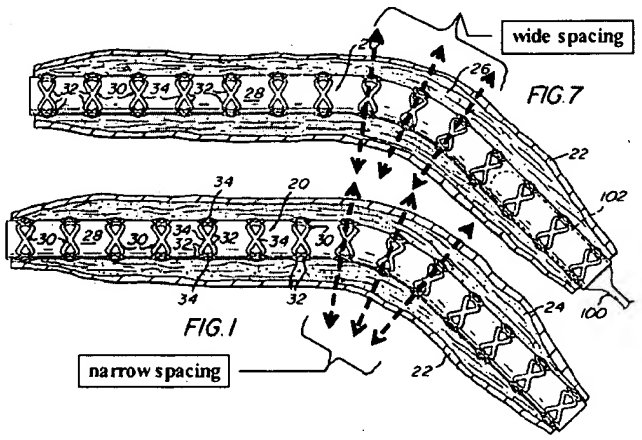
[1] helical *adj.* 1. Of or having the shape of a helix or spiral. 2. Having a shape approximating that of a helix. THE AMERICAN HERITAGE COLLEGE DICTIONARY 630 (3d ed. 1997)
helix *n.* 2. A spiral form or structure. *Id.*
spiral *adj.* 3. Coiling around an axis in a constantly changing series of planes; helical. *Id.* at 1312.

[2] wound *v.* P.t. and p.part. of wind[2]. *Id.* at 1557
wind[2] *v.* 2. To wrap or encircle (an object) in a series of coils; entwine. *Id.* at 1545

independent claim 1. Independent claim 1 requires, *inter alia*, that the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature.

In Figures 1 and 7, Rhodes clearly shows that its stent members are not evenly and constantly distributed through its area of curvature. The stents members are clearly relatively closer to each other at the lower portion of the bend in Figures 1 and 7, and are clearly relatively spaced further apart at the upper portion of the bend in Figures 1 and 7. This is in direct contrast to the claimed limitations of the independent claims of the subject application. For the convenience of the Board Figures 1 and 7 are reproduced below with vectors added showing the discontinuity of the stent elements of Rhodes through areas of curvature of its stent, as follows:



Thus, Rhodes fails to disclose each and every limitation of the endoluminal prosthesis as set forth in independent claim 1. Further, Rhodes fails to teach or suggest that its stent members may be evenly and constantly distributed through its area of curvature. Therefore, claims 1-9, 13, 15, 17-22 and 44-45 are patentably distinct over Rhodes.

Claims 23, 24, 27, 29, 31, 33-37 and 42-43

Rhodes describes an intraluminal graft having a plurality of stents. The stents do not include undulating wires, but rather are pivotally connected straight stent struts. Rhodes describes it stents, as follows:

> **[E]ach stent member 30 basically comprises a plurality of interconnected links or struts 32. Each of the links is an elongated rigid member formed of stainless steel or some other suitable biocompatible material, e.g., tantalum, plastic. Each link has a pair of ends 32A and 32B and is joined to an associated link via a pivotable joint 34. Each joint 34 is made up of one end 32A of one link and the other end 32B of the immediately adjacent link. The link ends 32A and 32B are connected by any suitable means, e.g., a deformable member, a pin, etc., to enable the links to pivot outward with respect to each other so that the angle therebetween increases, yet which precludes the links from pivoting backward toward each other. When so arranged the links form a zig-zag pattern.** (Rhodes, column 6, lines 32-46) (emphasis added)

Such description is consistent with the detailed stent drawings of Rhodes, i.e. Figures 8 and 9, which are reproduced below for convenience of the Board.

FIG.8

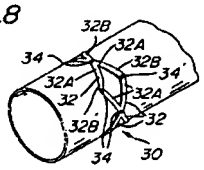
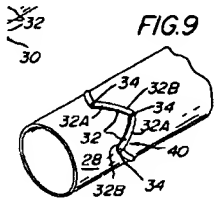


FIG.9



The straight elongate strut members of Rhodes do not read on the stents of the invention as set forth in the independent claims because the straight and elongated strut members of Rhodes are not helically wound undulating wires. Even though the straight struts of Rhodes are described as being pivotally connected, such connections do not make those straight struts as being helical[3] struts or wound[4] struts because the straight, short struts are merely diagonally

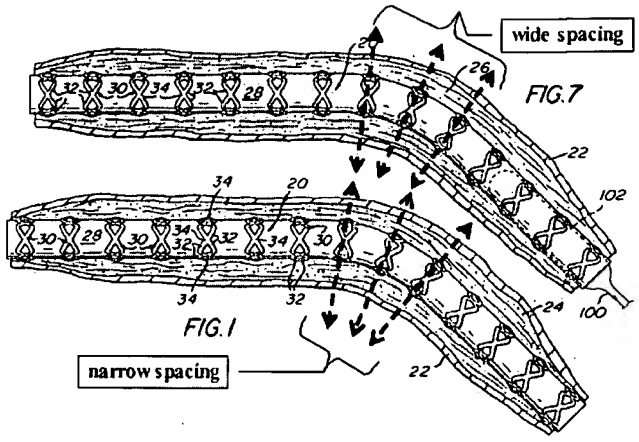
[3] See footnote 1.
[4] See footnote 2.

disposed over a minor portion wall. Further, none of the straight wire segments themselves of Rhodes have alternating peaks and valleys as the wires are described as being straight segments.

Thus, Rhodes fails to disclose, *inter alia*, a stent scaffold having V-shaped or quadrilateral-shaped cells consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat as set forth in independent claim 23.

Assuming *arguendo* that one could somehow read the strut members of Rhodes to be undulating wires, Rhodes still fails to disclose each and every limitation as set forth in independent claim 23. Independent claim 23 requires that the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature.

In Figures 1 and 7, Rhodes clearly shows that its stent members are not evenly and constantly distributed through its area of curvature. The stents are clearly relatively closer to each other at the lower portion of the bend in Figures 1 and 7, and are clearly relatively spaced further apart at the upper portion of the bend in Figures 1 and 7. This is in direct contrast to the claimed limitations of the independent claims of the subject application. For the convenience of the Board Figures 1 and 7 are reproduced below with vectors added showing the discontinuity of the stent elements of Rhodes through areas of curvature of its stent, as follows:



Moreover, with respect to independent claim 23, Appellant respectfully submits that the phrase "wherein the wires have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel" is not a statement of mere intended use, but is rather a structural limitation. Claim 23 clearly states, *inter alia*, that "the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature." Claim 23 further states that the segment of curvature comprises "an inside [segment] of the curvature and an outside [segment] of the curvature." Thus, claim 23 defines the positioning of the stent elements in an area of curvature. When the stent is a longitudinally straight orientation, e.g., disposed on a straight mandrel, the above substantially equal orientation of the undulating wires and their turns are not maintained, but are shifted as recited. Thus, claim 23 reads that in one stent orientation, the stent elements have a first structural orientation and in a second orientation the stent elements have a second structural orientation. Appellant respectfully submits that such limitations in claim 23 are not mere statements of intended use, but are structural limitations.

The final office action relies on two court cases dealing with intended use of devices. In one case an applicant had claimed a machine and had argued that a prior art machine performed a different task. *In re Casey*, 152 USPQ 235, 238 (CCPA 1967). The court ruled

that the "manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself". *Id.* In the second case, an applicant had argued that a claimed hair curling device would operate differently and would further operate with a different hair curling composition than a prior art device. *In re Otto, Otto and Briton*, 136 USPQ 458, 459 (CCPA 1967). Again the court ruled that the structure of the device is the issue and not its intended use. *Id.* at 460. In contrast, the limitations of claim 23 set forth two different structural limitations, one limitation when the stent is curved and another limitation when the stent is not curved, i.e., straight. Unlike the cases cited by the final office action where no structural differences of devices were in themselves being argued, structural limitations are recited in independent claim 23 as opposed to mere statements of intended use as present in the above court cases.

It should be noted that the device of Rhodes is in direct contrast to the claimed structural limitations of claim 23. The stent elements of Rhodes are uniformly longitudinally disposed when the stent is in a straight condition, but are longitudinally skewed when the stent is in its curved orientation. For the reasons set forth above, the Board may not properly ignore such structural differences because the limitations of claim 23 are structural limitations and not statements of mere intended use.

Thus, Rhodes fails to disclose each and every limitation of the endoluminal prosthesis as set forth in independent claim 23. Further, Rhodes fails to teach or suggest that its stent members may be evenly and constantly distributed through its area of curvature. Therefore, claims 23, 24, 27, 29, 31, 33-37 and 42-43 are patentably distinct over Rhodes.

II. Rejection under 35 U.S.C. §103(a) over U.S. Patent No. 5,122,154 to Rhodes in view of U.S. Patent No. 4,994,071 to MacGregor

Claims 12, 14, 28 and 30

U.S. Patent No. 4,994,071 to MacGregor (hereinafter "MacGregor") is cited by the final office action for its teachings regarding different stent materials. MacGregor, however, fails to cure the deficiencies of Rhodes. MacGregor describes a bifurcated stent 10 having a main tubular body or lattice 16 and two tubular legs or lattices 20, 23. (MacGregor, column 3, lines 54-68, Fig. 1). The lattices 16, 20, and 22 have a series of loops 12, 12'', 12', respectively, which are depicted as undulating looped wires. (*Id.*) A longitudinally extending wire 24 interconnects loops 12 and 12' and further interconnects lattices 10 and 22. (MacGregor, column 4, lines 1-4). A second longitudinally extending wire 26 similarly interconnects loops 12 and 12'' and lattices 10 and 20. (MacGregor, column 4, lines 5-10).

The stent portion 16, 20 and 22 are depicted in Figs. 1 and 1A as being substantially straight members, i.e. having no segments of curvature along any longitudinal axis. The wires 24, 26 are substantially straight in the longitudinal direction, i.e., not undulating wires, except for a bend at the point of bifurcation. (MacGregor, column 4, lines 10-14; Fig. 1). Thus, as depicted in Fig. 1, the wires 24, 26 are not undulating wires, and these non-undulating wires do not have turns that are distributed substantially equal along the length of the stent because the wires have only one bend at the point of bifurcation.

Further, MacGregor fails to describe that any of the loops 12, 12', 12", or undulating wires, may extend through the area of bifurcation, i.e., curvature. In other words, there is a discontinuity of the stent configuration at the area of bifurcation. (see e.g., MacGregor, Fig. 1A). The general depictions of Figs. 2A-3D, which schematically show the placement of the MacGregor stent within body vessels 50, 50a, 50b, depict portions of the stent being curved, but fail further detail the area of bifurcation, i.e., fails to show any wires and their turns being

distributed substantially equally along the length of the device, including being distributed substantially equally and uniformly along the portion of curvature.

Thus, MacGregor fails to cure the deficiencies of Rhodes because the wires 24, 26 of MacGregor only have one turn at the point of bifurcation and the turn is not therefore equally distributed along the length of the stent. Further, the stent coils 12, 12', 12'' of MacGregor are not equally distributed over the length of the stent due to discontinuity at the point of bifurcation.

Accordingly MacGregor fails to cure the deficiencies of Rhodes. Thus, Rhodes and MacGregor, individually or in combination, fail to teach or suggest the present invention. Therefore, claims 12-14 and 28 and 30 are patentably distinct over Rhodes and MacGregor.

III. Rejection under 35 U.S.C. §103(a) over U.S. Patent No. 5,122,154 to Rhodes in view of U.S. Patent No. 4,553,545 to Maass et al.

Claims 11 and 27

U.S. Patent No. 4,553,545 to Maass et al. (hereinafter "Maass") is cited by the final office action for its teaching of shape memory alloy stent materials. Maass, however, describes a helically shaped coil spring or stent. (Maass, column 1, lines 9-12; Figs. 1-6). Thus, Maass, fails to teach or suggest, *inter alia*, a stent scaffold having V-shaped or quadrilateral-shaped cells, where the stent scaffold consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat. Further, Maass fails to teach or suggest such a stent scaffold as having the wires and their turns being distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature.

Thus, Rhodes and Maass, individually or in combination, fail to teach or suggest the present invention. Therefore, claims 11 and 27 under 35 U.S.C. §103(a) are patentably distinct over Rhodes and Maass.

Thus, for the reasons set forth herein, claims 1-9, 11-15, 17-24, 27-31, 33-37 and 42-45 are patentably distinct.

Respectfully submitted,

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VIII. Claims Appendix

Claim 1. (Previously presented): An endoluminal prosthesis comprising:

a proximal end, a distal end and a hollow tubular body comprising a stent scaffold having V-shaped or quadrilateral-shaped cells, the stent scaffold consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat;

the hollow tubular body comprising at least one segment of curvature;

the segment of curvature comprising an inside of the curvature and an outside of the curvature;

wherein the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature, to provide a constant pitch of the wires therealong.

Claim 2. (Previously presented): The prosthesis of claim 1 wherein the segment of curvature is curved in at least one plane with respect to the central axis of the body.

Claim 3. (Previously presented): The prosthesis of claim 1 wherein the segment of curvature is curved in at least two planes with respect to the central axis of the body.

Claim 4. (Previously presented): The prosthesis of claim 1 wherein the hollow tubular body has at least two segments of curvature wherein the segments of curvature are located in successive progression along the body of the prosthesis and the segments are curved within the same plane of curvature.

Claim 5. (Previously presented): The prosthesis of claim 1 wherein hollow tubular body has at least two segments of curvature wherein the segments of curvature are located in successive progression along the body of the prosthesis and the segments are curved within different planes of curvature.

Claim 6. (Previously presented): The prosthesis of claim 1 wherein the hollow tubular body has at least two segments of curvature wherein the segments of curvature overlap at least a portion of one another and the segments of curvature are curved within different planes of curvature.

Claim 7. (Original): The prosthesis of claim 1 comprising both segments of curvature which overlap and segments of curvature which do not overlap.

Claim 8. (Original): The prosthesis of claim 1 wherein the prosthesis comprises at least one segment of curvature to approximate an anatomical shape.

Claim 9. (Original): The prosthesis of claim 8 wherein the prosthesis approximates the anatomical shape of the anatomical site intended for placement of the prosthesis.

Claim 10. (Canceled)

Claim 11. (Previously presented): The prosthesis of claim 1 wherein the wires comprise a shape memory alloy.

Claim 12. (Previously presented): The prosthesis of claim 1 wherein the wires comprise a super elastic alloy.

Claim 13. (Previously presented): The prosthesis of claim 1 wherein the wires comprise a polymer.

Claim 14. (Previously presented): The prosthesis of claim 1 wherein the wires are nitinol.

Claim 15. (Previously presented): The prosthesis of claim 1 wherein the peaks of adjacent undulating wires are interconnected.

Claim 16. (Canceled)

Claim 17. (Original): The prosthesis of claim 1 wherein the hollow tubular body comprises a thin-walled tube material wherein the center of the thin-walled tube provides the center of the prosthesis.

Claim 18. (Original) The prosthesis of claim 1 wherein the prosthesis further comprises at least one taper along the length of the body.

Claim 19. (Original): The prosthesis of claim 1 wherein the prosthesis further comprises at least one aperture on the body between the proximal end and the distal end.

Claim 20. (Original): The prosthesis of claim 1 wherein the prosthesis further comprises at least one non-circular cross-section along the length of the body.

Claim 21. (Original): The prosthesis of claim 1 wherein the prosthesis further comprises at least one branch of the prosthesis that extends away from the body of the prosthesis.

Claim 22. (Original): The prosthesis of claim 1 wherein at least a portion of the prosthesis is covered with a graft covering.

Claim 23. (Previously presented): An endoluminal prosthesis comprising:

a proximal end, a distal end and a hollow tubular body comprising a stent scaffold having V-shaped or quadrilateral-shaped cells consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat;

the hollow tubular body comprising at least one segment of curvature;

the segment of curvature comprising an inside of the curvature and an outside of the curvature;

wherein the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature;

wherein the wires have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel;

and further wherein the hollow tubular body is geometrically shaped and sized to approximate an anatomical shape.

Claim 24. (Original): The prosthesis of claim 23 wherein the prosthesis approximates the anatomical shape of the anatomical site intended for placement of the prosthesis.

Claim 25-26 (Canceled)

Claim 27. (Previously presented): The prosthesis of claim 23 wherein the wires comprise a shape-memory alloy.

Claim 28. (Previously presented) The prosthesis of claim 23 wherein the wires comprise a super elastic alloy.

Claim 29. (Previously presented): The prosthesis of claim 23 wherein the wires comprise a polymer.

Claim 30. (Previously presented): The prosthesis of claim 23 wherein the wires are nitinol.

Claim 31. (Previously presented) The prosthesis of claim 23 wherein the peaks of adjacent undulating wires are interconnected.

Claim 32. (Canceled)

Claim 33. (Original): The prosthesis of claim 23 wherein the hollow tubular body comprises a thin-walled tube material wherein the center of the thin-walled tube provides the center of the prosthesis.

Claim 34. (Original): The prosthesis of claim 23 wherein the prosthesis further comprises at least one taper along the length of the body.

Claim 35. (Original): The prosthesis of claim 23 wherein the prosthesis further comprises at least one aperture on the body between the proximal end and the distal end.

Claim 36. (Original): The prosthesis of claim 23 wherein the prosthesis further comprises at least one non-circular cross-section along the length of the body.

Claim 37. (Original): The prosthesis of claim 23 wherein the prosthesis further comprises at least one branch of the prosthesis that extends away from the body of the prosthesis.

Claims 38-41 (Canceled)

Claim 42. (Previously presented): The prosthesis of claim 23 wherein the increased pitch at the outside segment is relative to the reduced pitch at the inside segment.

Claim 43. (Previously presented): The prosthesis of claim 23 wherein the wires and their turns have a constant pitch along the length of the segment of curvature.

Claim 44. (Previously presented): The prosthesis of claim 1 wherein the wires have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel.

Claim 45. (Previously presented): The prosthesis of claim 44 wherein the increased pitch at the outside segment is relative to the reduced pitch at the inside segment.

IX. Evidence Appendix

There were no declarations or other evidence submitted during the prosecution of this application.

X. Related Proceedings Appendix

None